**REVIEW ARTICLE**

Methods used in the selection of instruments for outcomes included in core outcome sets have improved since the publication of the COSMIN/COMET guideline

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Abstract

Objectives: Once a core outcome set (COS) has been defined, it is important to achieve consensus on how these outcomes should be measured. The aims of this systematic review were to gain insight into the methods used to select outcome measurement instruments and to determine whether methods have improved following the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN)/Core Outcome Measures in Effectiveness Trials (COMET) guideline publication.

Study Design and Setting: Eligible articles, which were identified from the annual COMET systematic review, concerned any COS development studies that provided a recommendation on how to measure the outcomes included in the COS. Data were extracted on the methods used to select outcome measurement instruments in accordance with the COSMIN/COMET guideline.

Results: Of the 118 studies included in the review, 48% used more than one source of information when finding outcome measurement instruments, and 74% performed some form of quality assessment of the measurement instruments. Twenty-three studies recommended one single instrument for each core outcome included in the COS. Clinical experts and public representatives were involved in selecting instruments in 62% and 28% of studies, respectively.

Conclusion: Methods used to select outcome measurement instruments have improved since the publication of the COSMIN/COMET guideline. Going forward, COS developers should ensure that recommended outcome measurement instruments have sufficient content validity. In addition, COS developers should recommend one instrument for each core outcome to contribute to the overarching goal of uniformity in outcome reporting. © 2020 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Keywords: Core outcome set; COS; Development; Outcome measurement instrument; Selection; Methodology

1. Introduction

There is lack of consensus with regard to the selection of outcomes and outcome measurement instruments for clinical trials, which causes inconsistencies in the outcomes reported and difficulties in comparing these outcomes in systematic reviews and meta-analyses [1]. In addition, there is great variability in the quality of outcome measurement instruments used, and it is not always clear if the best instrument is being used for a given outcome. To overcome these issues, standardization of the selection of outcomes and outcome measurement instruments is needed.

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What is new?**Key findings**

- Methods used to select core outcome measurement instruments vary across studies, with many studies not meeting the recommended standards.
- Methods used to select outcome measurement instruments have improved since the publication of the COnsensus-based Standards for the selection of health Measurement INstruments/Core Outcome Measures in Effectiveness Trials guideline.

What this adds to what was known?

- This is the first study to assess how the outcome measurement instruments recommended in existing core outcome sets have been selected and whether good practices are being followed.

What is the implication and what should change now?

- Core outcome set developers need to make better use of the guidance available when agreeing on how to measure the outcomes included in core outcome sets.
- Developers need to ensure that outcome measurement instruments are of sufficient quality and especially have sufficient content validity.

The Core Outcome Measures in Effectiveness Trials (COMET) Initiative (www.comet-initiative.org), launched in January 2010, aims to facilitate the development and application of agreed standardized sets of outcomes, also known as “core outcome sets” (COSs). A COS is an agreed minimum set of outcomes that should be measured and reported in all clinical trials of a specific disease or trial population (i.e., what to measure) [1]. Once the COS has been defined, it is then important to achieve consensus on how these outcomes should be measured (i.e., how to measure).

The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) initiative (<http://www.cosmin.nl/>) aims to improve the selection of outcome measurement instruments. (When using the term “outcome measurement instruments,” we are referring to any instruments, definitions, tools, procedures, etc., that are used to measure an outcome.) In 2016, COSMIN and COMET published a consensus-based guideline on how to select outcome measurement instruments for outcomes included in a COS [2]. Among a large group of international stakeholders from 14 different countries, including clinicians, clinimetricians/psychometricians, epidemiologists, journal editors, physicians, researchers, and statisticians, consensus was obtained on methods for selecting

outcome measurement instruments for outcomes included in a COS. COS developers are guided through the process of instrument selection in four consecutive steps: Step 1, conceptual considerations; Step 2, finding existing outcome measurement instruments; Step 3, quality assessment of outcome measurement instruments; and Step 4, recommendations on the selection of outcome measurement instruments. It is unknown, however, how the outcome measurement instruments recommended in existing COS have actually been selected by COS developers and whether good practices for COS development, as described in the COSMIN/COMET guideline are being followed.

The aims of this systematic review were to (1) gain insight into the methods used by COS developers for selecting core outcome measurement instruments and (2) determine whether the methods have improved following the 2016 publication of the COSMIN/COMET guideline. It is hypothesized that the quality of the methods used to select the core outcome measurement instruments varies considerably, and it is therefore anticipated that there will be considerable room for improvement in COS development with regard to instrument selection. However, there are expected to be improvements in the methods used in studies that have been published from 2017 onward.

2. Methods**2.1. Eligibility criteria**

Eligible articles concern COS development studies that provide recommendations on what and how to measure, either done together in one study or done in two separate stages (i.e., two or more studies). We included all COS studies, identified from the original COMET systematic review and annual updates [3–8], that provided a recommendation on the instruments to measure the outcomes included in the COS. COS development studies that only provide a recommendation on what to measure, but do not consider how to measure, and studies that discuss how to measure the outcomes but do not give a recommendation were excluded.

2.2. Literature search

The search strategy for identifying eligible COS development studies has been described elsewhere in detail [3–8]. In brief, a comprehensive search strategy to identify studies that aimed to define COS in any disease area was first developed in 2013 [3] (see [Appendix A](#) for full search strategy). Database searches were repeated in 2015 [4], 2016 [5], 2017 [6], 2018 [7], and 2019 [8].

2.3. Data extraction

Four sets of reviewers (C.A.C.P.–S.L.G., S.L.G.–M.S.-K., M.S.-K.–C.A.C.P., and S.L.G.–K.M.-S.) independently

extracted data on descriptive information for each identified COS, including the target population, disease area, and the (number of) outcomes. Data have been extracted in accordance with the COSMIN/COMET guideline (see flowchart in [Appendix B](#)). Methods used to select instruments for the COS have been extracted, including the approach taken to identify existing instruments, the evaluation of the quality and feasibility of instruments, the number of instruments recommended for use, arguments used for selecting instruments other than quality criteria (measurement properties), recommendations for additional research on instruments, and whether any guidance for instrument selection, including the COSMIN/COMET guideline, was followed (see [Appendix C](#)). To ensure consistency in data extraction, the data extraction form was pilot tested for a set of five studies, and the extracted data were compared before extracting data for the remaining studies. Discrepancies in data extraction between pairs of reviewers were sought to be resolved by discussion with the third reviewer, and consensus was reached.

To improve the quality of our data, first authors of the included studies were contacted in person by email to verify the data extracted from their studies, and they were asked to provide additional information that might be missing. In case the email could not be delivered, the last author of that particular study was contacted by email. References of the included papers were also checked to identify any other relevant articles on instrument selection for COS.

3. Results

A total of 163 articles describing 118 COS development studies were included in the review. A flow diagram of the article and abstract selection process is provided in [Fig. 1](#), guided by Preferred Reporting Items for Systematic Reviews and Meta-Analyses [9].

Details on COS development studies (e.g., target population, disease area) can be found in [Appendix D](#). In summary, COSs were developed in a variety of geographical locations, including Asia, Canada, Europe, New Zealand,

South Africa, South America, and the United States. All COSs were developed in the English language. The number of core outcomes included in the COS varied between 2 [10,11] and 26 [12]. Following the COMET classifications [13], COS were developed in 24 different disease areas, mostly neurology ($n = 19$ studies), rheumatology ($n = 14$), heart and circulation ($n = 13$), and orthopedics and trauma ($n = 11$). In 36 studies, the COS were developed for adults; in 17 studies for children and in 20 studies for both adults and children. In 45 studies (38%), the age group for which the COS was developed was not specified. Of the 118 studies, 23 studies reported on core outcomes for different subgroups of patients, such as age groups [14–16], acute or chronic conditions [17], disease severity [18,19], type of study (e.g., prevention trials vs. intervention trials [20,21] or phase I–II vs. phase III clinical trials [15]); for acute vs. long-term treatment [22] or acute treatment vs. prophylaxis [23–25]; for different diseases/conditions [16,26–32]; or for different settings [33,34].

3.1. Methods used in the selection of instruments for COS

With regard to COS development, 87 of 118 COS studies used a single process to identify the core outcomes as well the instruments recommended to measure these outcomes; whereas 31 studies used a two-stage process that involved first agreeing on “what to measure” (select core outcomes) before moving onto the “how to measure” (recommend instruments).

3.1.1. Finding existing outcome measurement instruments

It is recommended that COS developers aim for finding all existing outcome measurement instruments. Multiple sources of information can be used to find instruments: (1) performing a systematic review, including a search in MEDLINE (and EMBASE); (2) use existing review(s); (3) reference lists; (4) expert opinion; or (5) other sources of information, such as online databases, book (chapters), or conference proceedings [2]. Of the 118 included studies, 21 studies (18%) used three or more sources of information when finding existing outcome measurement instruments, and 36 studies (30%) used two sources of information. Sixty-one studies (52%) used only one source of information when finding existing outcome measurement instruments, with 39 of 61 studies accessing expert opinion only. Of the 118 studies, 52 studies (44%) performed a systematic review; 19 studies (16%) used an existing review; seven studies (6%) searched reference lists; 49 studies (42%) accessed expert opinion; and 15 studies (13%) used other sources of information, mostly instruments used in clinical trials.

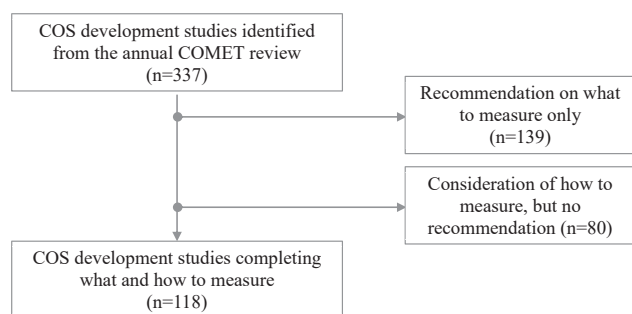


Fig. 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart of identification of eligible studies from the Core Outcome Measures in Effectiveness Trials database.

3.1.2. Quality assessment of outcome measurement instruments

COS developers should base their recommendations for outcome measurement instruments on (1) the quality of the existing outcome measurement instruments, that is, their measurement properties (including an evaluation of the quality of the validation studies), and (2) the feasibility aspects of the outcome measurement instruments [2].

3.1.2.1. Measurement properties. It is recommended that evidence on the measurement properties of outcome measurement instruments should be available in the target population. The quality of instruments is determined in studies on measurement properties, which should be of high methodological quality. Of the 118 studies, six studies (5%) [35–40] considered both the results of the measurement properties of the outcome measurement instruments and the quality of studies on these measurement properties. However, in three of these studies [35,36,38], it remains unclear whether a best evidence synthesis was performed. COS developers of 23 of 118 studies (20%) only considered the results of the measurement properties of the included outcome measurement instruments but did not consider the quality of the studies on these measurement properties. In 58 of 118 studies (49%), COS developers referred to quality criteria of outcome measurement instruments; however, there was no mention of any formal assessment of whether the instruments met these criteria. COS developers of 31 of 118 studies (26%) did not take the quality of the outcome measurement instruments into account when making their recommendations.

3.1.2.2. Feasibility. Of the 118 studies, 74 studies (63%) have taken feasibility aspects into consideration in the selection of instruments for the COS, such as availability of the instrument, cost of an instrument, ease of administration, and length of an instrument. In 44 studies (37%), there was no indication that feasibility was taken into consideration in the selection of instruments for the COS.

3.1.3. Recommendations on the selection of outcome measurement instruments

It is advised to recommend only one outcome measurement instrument for each core outcome per subdomain/subpopulation in the COS, as this will serve the ultimate goal of standardization of outcome reporting [2]. Of the 118 studies, only 11 studies (9%) recommended one single instrument for each core outcome included in the COS [12,38,39,41–48]. In seven of these 11 studies, one instrument was selected for each core outcome (range: 4–26) in the COS [12,38,41,43,44,47,48]. In three studies, one instrument was recommended for each core outcome or for each subpopulation (i.e., children and adolescents; range of core outcomes: 4–10) [42,45,46]. In one study, one instrument was recommended for each of the four core outcomes, with two alternative instruments recommended for

two of the outcomes because they were free of charge [39]. In 12 of the 118 studies (10%), one single instrument was recommended for each core outcome other than those for which no outcome measurement instrument could be recommended (range of core outcomes with instrument recommended: 1–17) [21,37,49–58]. Twelve of the 118 studies (10%) recommended one instrument for all included core outcomes except one (range included core outcomes: 3–15) [25,35,40,59–67]. Another seven studies (6%) recommended multiple instruments for all core outcomes included in the COS [19,36,68–72]. In 76 of 118 studies (64%), a combination of recommendations was used in the selection of instruments for each core outcome included in the COS (i.e., for some outcomes, one instrument was recommended; for some outcomes, multiple instruments were recommended, either for the entire group or for different subgroups; and for some outcomes, no instrument was recommended).

3.1.4. Consensus procedure used to reach agreement

It is recommended that COS developers use a consensus procedure to get final agreement on the selected instruments included in the COS [2]. In 80 of 118 studies (68%), a consensus procedure was used. In 30 of 80 studies, it was unclear and not specified how consensus was obtained. In 8 of 80 studies, COS developers used a Delphi technique to reach consensus on the selection of core instruments [12,43,48,64,73–76]. Six of the 80 studies were guided by the Outcome Measures in Rheumatology (OMERACT) consensus and validation process, which involved participants voting and then breaking out into groups to review and discuss domains and instruments [39,40,63,72,77,78]. In 36 of 80 studies, COS developers conducted a consensus meeting, including various methods, to reach consensus on the core instruments. Consensus methods used at the meetings included presentations, nominal group techniques, group discussions, consensus workshops, breakout sessions, and voting. In 38 of 118 studies (32%), no consensus procedure was used to agree on the instruments included in the COS, and recommendations were formulated by the COS developers.

3.1.5. Stakeholders involved in the selection of outcome measurement instruments

Of the 118 studies, the following stakeholders were involved in the selection of outcome measurement instruments: clinical experts ($n = 73$), nonclinical researchers ($n = 39$), patients and/or public representatives ($n = 33$), regulatory authorities ($n = 20$), and industry representatives ($n = 17$). An additional 43 studies did not provide any details about the stakeholders involved in selecting the outcome measurement instruments. Table 1 displays the different stakeholder combinations across the 118 studies.

Table 1. Number of studies involving each stakeholder group combination

Stakeholder groups	n (%)
Clinical experts	19 (16)
Clinical experts, public representatives, and nonclinical research experts	11 (9)
Clinical experts and nonclinical research experts	8 (7)
Clinical experts and public representatives	7 (6)
Clinical experts, public representatives, nonclinical research experts, and industry experts	6 (5)
Clinical experts, public representatives, nonclinical research experts, authorities, and industry experts	4 (3)
Clinical experts, public representatives, nonclinical research experts, and authorities	3 (3)
Clinical experts, nonclinical research experts, and authorities	3 (3)
Clinical experts, authorities, and industry experts	3 (3)
Clinical experts, public representatives, and authorities	2 (2)
Clinical experts and authorities	2 (2)
Clinical experts and other	2 (2)
Clinical experts, nonclinical research experts, authorities, and industry experts	2 (2)
Clinical experts and industry experts	1 (1)
Nonclinical research experts, authorities, and industry experts	1 (1)
Nonclinical research experts	1 (1)
No details provided	43 (36)

3.1.6. Guidance on instrument selection

In 35 of 118 studies (30%), published guidance for instrument selection was used. Most studies ($n = 13$) used the OMERACT guidance [79], whereas other studies used the Grading of Recommendations, Assessment, and Evaluation approach [16,80]; Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials recommendations [81,82]; World Health Organization—International Classification of Functioning, Disability and Health framework [83,84]; European League Against Rheumatism operating procedures [85]; and International Consortium for Health Outcomes Measurement framework [12,48,64]. Four studies used the COSMIN/COMET guideline [39,40,76,84], and a fifth study [37] used the COSMIN standards for the selection of health status measurement instruments [86]. Eleven studies [11,17,32,36,87–93] referred to other guidance, for example, guidelines from European Crohn's and Colitis Organisation guidelines committee; guidance by Physical Rehabilitation Outcomes Measures, published by the Canadian Physiotherapy Association; previous work by Hudak et al. [94] or

Dworkin et al. [95]; other consensus guidelines [96–101]; the Harmonizing Outcome Measures for Eczema (HOME) roadmap [102]; the framework for the selection of clinical trial indices proposed by Tugwell and Bombardier [103]; and guidance from a qualitative evaluation of measures for psychosocial intervention in dementia care. No guidance was used in 43 of 118 studies (37%), whereas in 40 of 118 studies (34%), it remains unclear whether any form of guidance was used.

3.1.7. Recommendations for additional research on instruments

In 55 of 118 studies (47%), recommendations were made for additional validation studies ($n = 31$) or development of new instruments ($n = 24$).

3.2. Differences between studies published before and after the publication of the COSMIN/COMET guideline

Of the 118 studies included in this review, 92 studies (78%) were published before the publication of the

COSMIN/COMET guideline, and 26 studies (22%) were published after its publication. Table 2 provides a comparison of the methods used in studies published before and after the publication of the COSMIN/COMET guideline. Studies published after the publication of the COSMIN/COMET guideline were more likely to base their recommendations on the quality of the outcome measurement instruments, with 8 of 26 studies (31%) considering the evaluation of the measurement properties of the instruments and a further 4 of 26 studies (15%) considering both the quality of the measurement properties of the outcome measurement instruments and the quality of studies on measurement properties. In addition, these studies were also more likely to comply with the COSMIN/COMET recommendations on the selection of outcome measurement instruments, with 11 of 26 studies (42%) recommending one single instrument for each core outcome included in the COS, for which a recommendation could be made, and a further 6 of 26 studies (23%) recommending one instrument for all included core outcomes except one. The inclusion of stakeholders across all groups increased in the postguideline studies, with the biggest increase being the inclusion of patients and/or public representatives, which increased from 20% to 58%. There was also a 31% decrease in the number of studies that did not provide any details about stakeholder involvement. Regarding the use of guidance, 12 of 26 studies (46%) published following the COSMIN/COMET guideline used available guidance for instrument selection, with 5 of 26 studies (19%) specifically using the COSMIN/COMET guideline or other COSMIN guidance.

4. Discussion

We identified 118 COS development studies that provided recommendations for how to measure the outcomes included in a COS. Reviewing these studies has enabled us to gain insight into the methods used by COS developers to select outcome measurement instruments. After the publication of the COSMIN/COMET guideline, there has been an improvement in the methods used, specifically in relation to quality assessment, recommendations on the selection of instruments, stakeholder involvement, and the use of published guidance.

4.1. Finding all existing instruments

COS developers should make better use of the literature to inform their instrument selection process. Relying solely on expert opinion to find existing outcome measurement instruments, as 33% of studies did in the current review, may result in only the most commonly used instruments or those that are favored by clinicians, being considered. To assist developers in identifying instruments, COSMIN maintains a database of systematic reviews of outcome measurement

instruments [104]. The “COSMIN guideline for systematic reviews of patient-reported outcome measures” [105] can be used for performing a comprehensive literature search or full systematic review to find all available instruments if a good-quality systematic review is not available.

4.2. Quality assessment of instruments

COS developers should take both the quality of the studies on measurement properties and the results of the measurement properties of the outcome measurement instruments into account in their recommendations. This will ensure that the most reliable and valid outcome measurement instruments are selected. However, only 10 of the COS development studies included in this review considered both aspects. To assist in the assessment of the quality of the studies, COSMIN has developed a risk of bias checklist for use in systematic reviews of patient-reported outcome measures (PROMs) to assess the risk of bias of studies on measurement properties [106]. COSMIN has also proposed quality criteria for measurement properties of health status questionnaires to assist COS developers in assessing the quality of identified instruments [106].

In contrast to the assessment of measurement properties, the feasibility of the identified instruments was generally taken into consideration in the selection of outcome measurement instruments. We expect that the number of studies considering these feasibility aspects will continue to remain high, after the publication of the COSMIN/COMET guideline in 2016 [2].

4.3. Generic recommendations on the selection of outcome measurement instruments

COS developers should try to recommend only a single instrument for each individual outcome included in a COS, to contribute to the overarching goal of uniformity in outcome reporting, and to enhance the comparability of clinical trials. Exceptions can, however, be made for subpopulations, such as children and adults, and different instruments may be necessary for the different age groups.

COS stakeholder groups should include more representative stakeholders, including patients, when agreeing on the most appropriate outcome measurement instruments. Most COS stakeholder groups comprised clinical experts, whereas public representatives were involved in less than one-third of studies. This is concerning, as it suggests that the outcome measures recommended may not be those that public representatives deem to be most appropriate. Patients are increasingly being included in selecting the outcomes for inclusion in COS, with 92% of ongoing COS development studies in the COMET database planning to include some degree of patient input [107]. However, patients and/or public representatives were only included in the selection of outcome measurement instruments in 28% of COS studies.

Table 2. Methods used in studies published before and after the publication of the COSMIN/COMET guideline

COSMIN/COMET Guideline Task	Preguideline, n/N (%)	Postguideline, n/N (%)
Finding existing outcome measurement instruments		
Used three or more sources to find existing outcome measurement instruments	16/92 (17)	5/26 (19)
Used two sources to find existing outcome measurement instruments	30/92 (33)	6/26 (23)
Used one source to find existing outcome measurement instruments	46/92 (50)	15/26 (58)
Quality assessment of outcome measurement instruments		
(a) Measurement properties		
Considered both the quality of the measurement properties of the outcome measurement instruments and the quality of studies on measurement properties	2/92 (2)	4/26 (15)
Considered the evaluation of the measurement properties of the included outcome measurement instruments	15/92 (16)	8/26 (31)
Referred to quality criteria but no formal assessment	52/92 (57)	6/26 (23)
Quality of outcome measurement instruments not taken into account	23/92 (25)	8/26 (31)
(b) Feasibility		
Feasibility aspects taken into consideration	59/92 (64)	15/26 (58)
Recommendations on the selection of outcome measurement instruments		
One single instrument for each core outcome	3/92 (2)	8/26 (31)
One single instrument for each core outcome where a recommendation could be made	9/92 (10)	3/26 (12)
One instrument for all included core outcomes except one	6/92 (7)	6/26 (23)
Multiple instruments for all core outcomes	7/92 (8)	0/26 (0)
Combination of recommendations for each core outcome	67/92 (73)	9/26 (35)
Consensus procedure used to reach agreement		
Used consensus procedure to get final agreement on the selected instruments	62/92 (67)	18/26 (69)
Specified details of the consensus procedure	35/62 (56)	15/18 (83)
Stakeholders involved in the selection of outcome measurement instruments		
Clinical experts	50/92 (54)	23/26(88)
Patients and/or public representatives	18/92 (20)	15/26 (58)
Nonclinical researchers	26/92 (28)	13/26 (50)
Regulatory authorities	15/92 (16)	5/26 (19)
Industry representatives	13/92 (14)	4/26 (15)

(Continued)

Table 2. Continued

COSMIN/COMET Guideline Task	Preguideline, n/N (%)	Postguideline, n/N (%)
No details provided about the stakeholders involved in selecting the outcome measurement instruments	40/92 (43)	3/26 (12)
Guidance on instrument selection		
Used published guidance	23/92 (25)	12/26 (46)
Recommendations for additional research on instruments		
Made recommendations for the development of new instruments or additional validation studies	42/92 (46)	13/26 (50)

It could be argued that it is more difficult to include patients in the selection of outcome measurement instruments than in the selection of the outcomes because the selection of instruments is mostly based on studies on measurement properties, which may be difficult for patients to understand. COS developers may need to address additional issues when the population concerned includes people with cognitive impairment, communication difficulties, or other vulnerabilities, which make participation in such processes challenging. Despite the complexities involved in the selection of outcome measurement instruments, there has been an increase in the inclusion of patients and/or public representatives since the publication of the COSMIN/COMET guideline. Thus, it is certainly possible to involve patients and/or public representatives, including those from vulnerable groups, in this process. However, it should be acknowledged that these groups are likely to need additional support to participate, and so in some instances, a multi-stage approach, which allows for adequate support, might be necessary to ensure that engagement is meaningful. One potential means of involvement is for patients to judge the face and content validity (relevance, comprehensiveness, and comprehensibility) of the available outcome measurement instruments, which are considered the most important measurement properties [106,108]. However, it should be noted that this may not be necessary if previously published studies have assessed the validity of outcome measurement instruments with the population in question.

4.4. Implications

This review has highlighted that the methods used to select the core outcome measurement instruments vary across studies, with many studies not meeting the recommended standards. However, the majority of included studies were published before the development of the COSMIN/COMET guideline, in 2016, and so developers may have been unaware of methodology for selecting outcome measurement instruments. There have, however, been clear improvements in the methods used to select outcome measurement instruments in studies published since the publication of the COSMIN/COMET guideline. It is unclear

whether such improvements are a direct result of the publication of the COSMIN/COMET guideline or whether other variables are responsible for the pre- and post-guideline reporting differences. Other potential variables may include increased COS awareness prompting COS developers to be more thorough in the outcome measurement instrument selection process. In addition, the differences in the rate of inclusion of patients may be attributable to increased public input in health research in general.

Going forward, we hope that COS developers will use the COSMIN/COMET guideline, along with the other resources listed previously, to ensure that recommendations for outcome measurement instruments are developed using rigorous methodology. A recent paper by Ju et al. [109] highlights how to apply the COSMIN/COMET guidance when identifying outcome measurement instruments.

Apart from the COSMIN/COMET guideline, other guidelines can also be used to guide the selection of outcome measurement instruments for COS, for example, the OMERACT Handbook [110] or HOME roadmap [102]. Different guidelines put different emphasis on different steps of the process. For example, in contrast to the COSMIN/COMET guideline and HOME roadmap, the OMERACT process does not require a search to find all available instruments but starts with a selection of instruments that seem to have a good match with the target domain and are considered feasible. Both the COSMIN/COMET guideline and the OMERACT Handbook address the need for good content validity of outcome measurement instruments. Therefore, we suggest that, when resources are limited, COS developers should evaluate the content validity of available instruments, if this has not been done previously, with a small number of patients in their stakeholder group (e.g., ask patients to evaluate the relevance, comprehensiveness, and comprehensibility of all items/tests). The COSMIN methodology for assessing content validity of PROMs can be used for further guidance [108]. Nevertheless, it should be acknowledged that although guidelines are important, some flexibility should be used to best facilitate the participation of patients and/or public representatives.

4.5. Limitations

All the studies included in the current review were identified from the annual COMET systematic review of COS. We did not perform a systematic search for all studies relating to how outcomes should be measured. For example, COS groups may perform systematic reviews of outcome measurement instruments and select their instruments based on these reviews but may not publish a separate paper on the selection process for the outcome measurement instruments; therefore, we cannot be certain that we have identified all relevant studies. However, we did check the references of all included papers, and authors of COS studies were contacted to provide additional information.

5. Conclusions

In conclusion, COS developers need to make better use of the guidance available when agreeing on how to measure the outcomes included in COS. Specifically, developers need to ensure that outcome measurement instruments are of sufficient quality and especially have sufficient content validity. Furthermore, developers should aim to adhere to uniformity by selecting a single outcome measurement instrument for each outcome within a COS.

CRedit authorship contribution statement

Sarah L. Gorst: Investigation, Methodology, Writing - original draft, Writing - review & editing, Project administration. **Cecilia A.C. Prinsen:** Investigation, Methodology, Writing - original draft, Writing - review & editing, Project administration. **Maximilian Salcher-Konrad:** Investigation, Writing - review & editing. **Karen Matvienko-Sikar:** Investigation, Writing - review & editing. **Paula R. Williamson:** Conceptualization, Methodology, Writing - review & editing. **Caroline B. Terwee:** Conceptualization, Methodology, Writing - review & editing.

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Supplementary data

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